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UNITED STATES COURT OF APPEALS
TENTH CIRCUIT

PATRICK FISHER
Clerk

NATIONAL COUNCIL FOR
IMPROVED HEALTH, STANLEY
MALSTROM, CLIVE J.
BUCHANAN,

Plaintiffs-Appellants,

v.

DONNA SHALALA, Secretary of the
U.S. Department of Health and Human
Services; DAVID KESSLER,
Commissioner, U.S. food & Drug
Administration,

Defendants-Appellees.

No. 95-4151

AMERICAN CANCER SOCIETY,
AMERICAN HEART ASSOCIATION,
CENTER FOR SCIENCE IN THE
PUBLIC INTEREST, PUBLIC
CITIZEN, and CONSUMER
FEDERATION OF AMERICA,

Amici Curiae.

Appeal from the United States District Court
for the District of Utah
(D.C. No. 94-CV-509-G)

Kirkpatrick W. Dilling of Dilling and Dilling, Chicago, Illinois, (Michael J. Lennard, Karen A. Weaver, of Dilling and Dilling, Chicago, Illinois; M. Richard Walker and Ralph R. Tate, Jr., Salt Lake City, Utah, with him on the briefs) for Plaintiffs-Appellants.

Susan Strawn, Attorney, of Office of Consumer Litigation, Civil Division, U. S. Department of Justice, Washington, D.C., (Drake Cutini, Attorney, of Office of Consumer Litigation, Civil Division, U. S. Department of Justice, Washington, D.C.; Douglas Letter, Attorney, Appellate Staff, Civil Division, U. S. Department of Justice, Washington, D.C.; Margaret Porter, Chief Counsel, Philip S. Defler, Louisa T. Nickerson, Associate Chief Counsels, Food and Drug Administration, Rockville, Maryland, Of Counsel, with her on the brief) for Appellees.

(Allison M. Zieve, Public Citizen Litigation Group, Washington, D.C., [Bruce Silverglade, Center for Science in the Public Interest, Washington, D.C., with her on the brief] for *Amici Curiae*.)

Before **BALDOCK**, **HOLLOWAY**, and **MURPHY**, Circuit Judges.

MURPHY, Circuit Judge.

Plaintiffs, National Council for Improved Health (“NCIH”), Stanley Malstrom, and Clive J. Buchanan, bring a facial challenge to the constitutionality of 21 C.F.R. § 101.14, which requires sellers of dietary supplements to obtain Food and Drug Administration (“FDA”) authorization before labeling

supplements with “health claims.”¹ The district court dismissed plaintiffs’ complaint, ruling that the health claims regulations did not violate the First Amendment. Although the district court reached the merits of plaintiffs’ claims, we conclude that plaintiffs do not have standing and therefore **reverse** the district court’s order on standing and **vacate** the remainder of its decision on the constitutionality of the health claims regulations.

I. Background

In 1990 Congress enacted the Nutrition Labeling and Education Act of 1990 (“NLEA”) which amended the Federal Food, Drug and Cosmetic Act (“FDCA”). *See* Pub.L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. 301, 321, 337, 343, 371). The NLEA was passed to “clarify and to strengthen [FDA’s] authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about the nutrients in foods.” *See* H.R. Rep. No. 101-538, at 7 (1990), *reprinted in* 1990 U.S.C.C.A.N. 3336, 3337. The NLEA places limits on health claims that may be made on food and dietary supplement labels.

¹Plaintiffs also contend on the first page of their brief that the FDA “regulations” were promulgated “in excess of the statutory jurisdiction, authority and limitations of defendants.” Brief for Appellants at 1. Plaintiffs do not, however, present any argument or authority in support of this contention. The argument is therefore waived. *See United States v. Hardwell*, 80 F.3d 1471, 1492 (10th Cir.), *reh’g granted in part on other grounds*, 88 F.3d 897 (10th Cir. 1996).

Specifically, a claim may be asserted “in the label or labeling² of [a] food [that] . . . characterizes the relationship of any nutrient . . . to a disease or a health-related condition,” only if such claims are made in accordance with 21 U.S.C. § 343(r)(3), for foods in conventional form, or 21 U.S.C. § 343(r)(5)(D), for dietary supplements. 21 U.S.C. § 343(r)(1). Section 343(r)(5)(D) mandates that health claims “made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall . . . be subject to a procedure and standard . . . established by regulation.”

In response to section 343(r)(5)(D)’s mandate, the Food and Drug Association (“FDA”) promulgated 21 C.F.R. § 101.14 and 101.70.³ *See* 59 Fed. Reg. 395, 425 (1994). These regulations require persons desiring to make health claims on labels of dietary supplements to petition the FDA to authorize each claim. The FDA will promulgate regulations authorizing the petitioned-for health claim if the FDA

determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts

²“Labeling” is defined as “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. § 321(m).

³Section 101.70 sets forth only the procedural guidelines for obtaining FDA approval for a health claim, not the substantive standards for approval. It is therefore not prominent in our discussion.

qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

21 C.F.R. § 101.14(c) (1996).⁴ Thus, if the FDA finds that a proposed nutrient-disease relationship is supported by significant scientific agreement among experts, it will promulgate, through notice and comment procedures, a regulation authorizing claims to be made about that relationship. 21 C.F. R. § 101.14(d)(1). If the FDA determines that such agreement does not exist among experts, the claim will not be permitted. Plaintiffs assert that the health claims regulations violate their First Amendment right of free speech.

In the proceedings before the district court, defendants brought a motion to dismiss, arguing plaintiffs lacked standing and that the health claims regulations did not violate the First Amendment. The district court held that plaintiffs did have standing but agreed with defendants that the regulations were constitutional.

We review the district court's ruling on standing *de novo*. *Chrisman v.*

Commissioner of Internal Revenue, 82 F.3d 371, 372 (10th Cir. 1996).

⁴Pursuant to 1994 amendments to the NLEA, certain health claims for dietary supplements may be made without petitioning the FDA. 21 U.S.C. § 343(r)(6) (1996). These include statements that claim a benefit related to a classical nutrient deficiency disease, certain claims relating to the role of a nutrient or dietary ingredient intended to affect the structure or function of the human body, and claims describing general well-being from consumption of a nutrient or dietary ingredient. *Id.* Such claims are permitted if the manufacturer has “substantiation” that the claim is truthful and not misleading, and the product bears certain disclaimers. *Id.*

II. Standing

Article III of the Constitution grants federal courts authority to adjudicate only actual “Cases” and “Controversies.” U.S. Const. art. III, § 2; *United States Nat’l Bank v. Independent Ins. Agents of America, Inc.*, 508 U.S. 439, 446 (1993). To ensure the case or controversy requirement is met, the Supreme Court has held that a plaintiff must allege the following: that the plaintiff has suffered an “injury in fact”; that there is a causal connection between the injury and the challenged conduct; and that it is likely, not speculative, that the injury will be redressed by a favorable decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

Defendants challenge plaintiffs’ standing to bring the instant case under the first and third prongs of this test. They assert that plaintiffs have never alleged injury from the prohibition of any specific claim under the health claims regulations. Defendants rely upon plaintiffs’ failure to identify a single claim they wish to make that could possibly be prohibited under the regulations. Defendants also contend that plaintiffs lack standing because they have not alleged a credible, immediate threat of enforcement of the health claims regulations against them.

The district court ruled that although the plaintiffs had not identified a specific claim they wished to make, plaintiffs nevertheless had standing to challenge the regulations’ constitutionality. The district court’s ruling rested on

“the expanded notion of standing under the ‘overbreadth doctrine.’” 893 F. Supp. 1512, 1516 (D. Ut. 1995). The court apparently interpreted the overbreadth doctrine as dispensing with the general requirement that the challenger show its own concrete injury resulting from the challenged statute or regulation.⁵ The district court’s conclusion rested on a flawed interpretation of the overbreadth doctrine.

A. Overbreadth and Standing

To satisfy Article III’s case or controversy requirement, a litigant in federal court is required to establish its own injury in fact. Thus, under traditional constitutional notions, a litigant may invoke only its own constitutional rights and

⁵The cases cited in the district court opinion may have isolated language supporting the district court’s approach (*e.g.* *O’Connor v. City & County of Denver*, 894 F.2d 1210, 1214 (10th Cir. 1990) (“Parties ‘who have not actually engaged in protected activity are allowed to challenge a statute that inhibits others from engaging in protected speech or expression.’”)). The full text of each of the cases cited, however, makes clear that the overbreadth doctrine does not permit the plaintiff to bring an action without identifying its own concrete injury. Indeed, in each case that the district court cited, the plaintiff suffered its own concrete, justiciable injury, which provided standing to bring a facial challenge. *See Alexander v. United States*, 509 U.S. 544, 546 (1993) (plaintiff prosecuted for violating federal obscenity laws and the Racketeer Influenced and Corrupt Organizations Act (RICO), subsequently challenged constitutionality of RICO’s forfeiture provisions); *Forsyth County v. Nationalist Movement*, 505 U.S. 123, 127 (1992) (plaintiff who had been charged with a fee for rally permit challenged constitutionality of ordinance imposing such fee); *O’Connor*, 894 F.2d at 1213 (movie theaters and cashier challenged amusement licensing scheme after their licenses had been revoked). In none of these cases did the plaintiff bring a facial challenge without establishing its own identifiable injury to provide standing.

may not assert rights of others not before the court. *See Laird v. Tatum*, 408 U.S. 1, 14 n.7 (1972). Under the overbreadth doctrine, however, a litigant may assert rights of individuals not before the court whose First Amendment rights may otherwise be infringed by an overly broad statute or regulation.⁶ *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620, 634 (1980). Thus, “[i]t is well established in the area of freedom of expression an overbroad regulation may be subject to facial review and invalidation, even though its application in the case under consideration may be constitutionally unobjectionable.” *Forsyth County v. Nationalist Movement*, 505 U.S. 123, 129 (1992); *see also Alexander v. United States*, 509 U.S. 544, 555 (1993); *Broadrick v. Oklahoma*, 413 U.S. 601, 612 (1973).

⁶The overbreadth doctrine does not, however, apply to commercial speech. *Murphy v. Matheson*, 742 F.2d 564, 568 (10th Cir. 1984) (citing *Village of Hoffman Estates v. The Flipside, Hoffman Estates, Inc.*, 455 U.S. 489 (1982)). The rationale for this limitation was articulated in *Central Hudson Gas & Electric Corp. v. Public Serv. Comm’n*, 447 U.S. 557 (1980):

The overbreadth doctrine derives from the recognition that unconstitutional restriction of expression may deter protected speech by parties not before the court and thereby escape judicial review. This restraint is less likely where the expression is linked to “commercial well-being” and therefore is not easily deterred by “overbroad regulation.”

Id. at 565 n.8 (citations omitted) (quoting *Bates v. State Bar*, 433 U.S. 350, 381 (1977)). Because plaintiffs have not even alleged a justiciable injury, we do not reach the applicability of the overbreadth doctrine to this case.

The overbreadth exception to traditional notions of constitutional adjudication is based on a recognition that “the very existence of some broadly written laws has the potential to chill the expressive activity of others not before the court.” *Forsyth*, 505 U.S. at 129. Although the overbreadth doctrine permits a party to challenge a statute or regulation that has not been unconstitutionally applied to that party, it does not dispense with the requirement that the party itself suffer a justiciable injury. *Phelps v. Hamilton*, No. 95-3251, Slip Op. at 37 (10th Cir. 1997) (“[A] plaintiff bringing a facial challenge to a statute on First Amendment grounds must still satisfy the ‘injury in fact’ requirement in order to demonstrate standing.”); see 4 Ronald D. Rotunda & John E. Nowak, *Treatise on Constitutional Law: Substance and Procedure* § 20.8, at 35 (1992) (“The decision to grant standing is unrelated to the substantive first amendment determination of whether the statute is unconstitutionally overbroad.”).

The Supreme Court explained this distinction well in *Secretary of State of Maryland v. Joseph H. Munson Co.*, 467 U.S. 947 (1984). In *Munson*, the Court considered a facial challenge to a Maryland statute that prohibited charitable organizations from paying or agreeing to pay expenses exceeding 25% of an amount raised in a fundraising activity. *Id.* at 950. Munson, a professional for-profit fundraising company, brought a facial challenge under the First and Fourteenth Amendments. Munson had entered contracts that called for payment

in excess of 25% of funds raised for a given event, and the Secretary of State of Maryland had informed Munson it would be prosecuted upon failure to comply with the statute. In addition, a potential client of Munson's had expressed reluctance to enter a contract with Munson because of the statute's limitation. *Id.* at 954-55. Despite these injuries to Munson, it was not a charity and did not claim its own First Amendment rights had or would be infringed by the statute. *Id.* at 955. The Court nevertheless concluded that Munson had standing to raise First Amendment concerns affecting charities. The Court explained:

Facial challenges to overly broad statutes are allowed not primarily for the benefit of the litigant, but for the benefit of society--to prevent the statute from chilling the First Amendment rights of other parties not before the court. Munson's ability to serve that function has nothing to do with whether or not its own First Amendment rights are at stake. *The crucial issues are whether Munson satisfies the requirement of "injury in fact,"* and whether it can be expected satisfactorily to frame the issues in the case. If so, there is no reason that Munson need also be a charity. *If not, Munson could not bring this challenge even if it were a charity.*

Id. at 958 (emphasis added). The Court went on:

The requirement that a statute be "substantially overbroad" before it will be struck down on its face is a "standing" question only to the extent that if the plaintiff does not prevail on the merits of its facial challenge and cannot demonstrate that, as applied to it, the statute is unconstitutional, it has no "standing" to allege that, as applied to others, the statute might be unconstitutional.

Id. at 959.

Thus, although the overbreadth doctrine allows one whose First Amendment rights have not been violated to assert a facial challenge on behalf of

others whose rights may be infringed, it does not eliminate the need for the plaintiff to demonstrate its own cognizable injury in fact. Plaintiffs here have attempted to challenge the constitutionality of the health claims regulations without identifying any specific harm caused them by the regulations. Unlike *Munson*, which alleged its own identifiable injury and thereby provided the vehicle to bring a First Amendment facial challenge premised on the statute's overbreadth, plaintiffs have alleged no injury in fact and thus cannot raise constitutional issues pertaining to them or to anyone else.⁷

B. Concreteness and Particularity

As noted above, to establish injury in fact, a party must first and foremost establish an invasion of a legally protected interest that is concrete, particularized, and actual or imminent. *Arizonans for Official English v. Arizona*, 117 S. Ct. 1055 (1997) (quotations omitted). The Supreme Court addressed this aspect of

⁷The requirement that a plaintiff assert its own legal rights prevents a court from “premature interpretations of statutes in areas where their constitutional application might be cloudy, and it assures the court that the issues before it will be concrete and sharply presented.” *Secretary of State v. Munson*, 467 U.S. 947, 955 (1984) (citations omitted). The dangers of advisory opinions are clear in this case. For example, a critical issue in evaluating the constitutionality of commercial speech is whether the speech at issue is truthful or misleading. *See, e.g., Central Hudson*, 447 U.S. at 566 (“For commercial speech to come within [the First Amendment’s protections], it at least must concern lawful activity and not be misleading.”). Without knowing what claims plaintiffs seek to disseminate, this court cannot assess whether such claims are truthful and not misleading. Therefore, an analysis of this issue would rest on mere speculation.

standing in *United Public Workers v. Mitchell*, 330 U.S. 75 (1947). In *Mitchell*, employees of the federal executive civil service and the United Public Workers of America sought a declaratory judgment that a portion of § 9(a) of the Hatch Political Activity Act (providing “[n]o officer or employee in the executive branch of the Federal Government . . . shall take any active part in political management or in political campaigns”) was unconstitutional. *Id.* at 82.

Plaintiffs challenged the statute, *inter alia*, on First Amendment grounds, asserting it violated their rights of freedom of speech, the press, and assembly. Plaintiffs alleged a desire to engage in political campaigns and acts of political management, but did not allege specifically attempted but statutorily prohibited actions or statements. *Id.* at 82. The Supreme Court stated:

[T]he federal courts . . . do not render advisory opinions. For adjudication of constitutional issues, “concrete legal issues, presented in actual cases, not abstractions” are requisite. This is as true of declaratory judgments as any other field. . . .

The power of courts, and ultimately of this Court to pass upon the constitutionality of acts of Congress arises only when the interests of the litigants require the use of this judicial authority for their protection against actual interference. A hypothetical threat is not enough. *We can only speculate as to the kinds of political activity the appellants desire to engage in or as to the contents of their proposed public statements or the circumstances of their publication.*

Id. at 89-90 (footnotes omitted) (emphasis added).

The same is true here. Plaintiffs do not advance a single claim they wish to make, or receive, which could be prohibited under the health claims regulations.

Instead, plaintiffs make generalized assertions that they will be “adversely affected” by the health claims regulations. R. at 4. Such assertions are simply insufficient.⁸ When we are left to speculate as to the nature of the claim plaintiffs may desire to make, and the treatment such a hypothetical claim may receive under the regulations, plaintiffs have failed to allege a sufficient injury in fact.⁹ *See Wilson v. Glenwood Intermountain Properties, Inc.*, 98 F.3d 590, 596 (10th Cir. 1996) (holding purely abstract injury claims do not provide particular, direct,

⁸We have previously found standing where a plaintiff has not yet violated an ordinance but has “shown an unmistakable intention to engage in activities that are prohibited by each of the challenged ordinances.” *ACORN v. City of Tulsa*, 835 F.2d 735, 739 (10th Cir. 1987). In this case, however, there has been no showing of an “unmistakable intention” to make any particular claim at all, much less one that may be prohibited under the health claims regulations. Without allegations of a claim that could be affected by the regulations, no injury as envisioned by Article III has occurred.

⁹Plaintiffs have not specifically argued that the regulations chill their own speech. If they had made such an allegation, that alone would be insufficient to bestow standing. An allegation of inhibition of speech, without more, will not support standing. *Laird v. Tatum*, 408 U.S. 1, 13-14 (1972) (“Allegations of a subjective ‘chill’ are not an adequate substitute for a claim of specific present objective harm or a threat of specific future harm.”). All of the Supreme Court cases employing the concept of “chilling effect” involve situations in which the plaintiff had suffered actual or imminent concrete harm (past or immediately threatened) separate from the “chill” itself. *See United Presbyterian Church v. Reagan*, 738 F.2d 1375, 1378 (D.C. Cir. 1984) (collecting cases). The purpose of the chilling concept is to enable even those who have not been inhibited to vindicate the First Amendment interests of those who have. It is only in this respect that “‘chilling effect’ has anything to do with the doctrine of standing: It permits a person, who has standing to challenge governmental action because of the concrete harm it causes him, to assert a deficiency which may not affect him but only others.” *Id.* at 1379.

concrete injury necessary to confer standing). Without an allegation of specific, concrete harm, plaintiffs do not have standing.

C. Fear of Prosecution

Plaintiffs also lack standing because they have failed to allege a credible threat of prosecution. “When plaintiffs ‘do not claim that they have ever been threatened with prosecution, that a prosecution is likely, or even that a prosecution is remotely possible,’ they do not allege a dispute susceptible to resolution by a federal court.” *Babbitt v. United Farm Workers Nat’l Union*, 442 U.S. 289, 298-99 (1979) (quoting *Younger v. Harris*, 401 U.S. 37, 42 (1971)). Plaintiffs’ failure to specify a particular claim they wish to make or receive that is prohibited under the health claims regulations prohibits them from clearing this hurdle. When no potentially prohibited claim has been made, there is no possible violation of the health claims regulations and thus no possibility of prosecution. *United Farm Workers*, 442 U.S. at 298 (finding no standing where plaintiffs had not alleged an “intention to engage in a course of conduct . . . proscribed by statute [or regulation],” let alone any “credible threat of prosecution thereunder”); see *McColleston v. City of Keene*, 668 F.2d 617, 620-21 (1st Cir. 1982) (finding no standing where complaint failed to allege conduct in which plaintiffs intended to engage and alleged nothing more than speculative risk of prosecution).

Plaintiffs' failure to allege a credible threat of prosecution deprives them of standing.

III. Conclusion

Plaintiffs have not made allegations that establish they have suffered the required injury in fact to confer standing upon them to challenge the health claims regulations. Consequently, we **REVERSE** the district court's ruling on standing, **VACATE** the district court's judgment and order addressing the constitutionality of the health claims regulations, and **REMAND** to the district court to dismiss the Second Amended Complaint for lack of jurisdiction.